

## **Obstetrics and Gynecology Devices Panel**

Tuesday, May 22, 2001 – 10 a.m.-1 p.m.

### ***Room Air and Gas Emboli Associated with Operative Hysteroscopy***

#### Panel Discussion Questions

1. What are the underlying conditions that lead to the formation of room air and gas emboli during operative hysteroscopy with RF unipolar and/or bipolar electrosurgery?
  - How common are room air and/or gas emboli during operative hysteroscopy using RF ablation technologies?
  - Are the risks essentially the same, whether using bipolar or unipolar modes?
  - Are there other studies that should be done to understand this risk?
2. How can we improve our communication of risk, as well as recommended practices for reducing risk, e.g. labeling changes (if so, how?), published articles, clinical training, FDA public health advisory, etc.?
3. How can we improve reporting of events such as air/gas emboli? For instance, are there additional communication means that would facilitate MDR reporting?
4. Are there additional measures that can be taken by FDA, NIH, relevant professional societies, etc., that will further add to the understanding of the risks of air and gas emboli during operative hysteroscopy?

#### Background Materials

- VersaPoint bipolar electrodes:
  - Summary of “Consensus Statement” and appraisal of case reports
  - letters for withdrawal & reintroduction
- Ethicon laboratory work: gas production rates
- references
  - Brooks, P.G.: “Venous air embolism during operative hysteroscopy,” in *Complications of Laparoscopy and Hysteroscopy*. Edited by R.S. Corfman, M.P. Diamond, A.H. DeCherney. Boston, Blackwell, p 212-215, 1993.
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- Hebbard, P.D., "Venous embolism in diathermy evolved gases complicating endometrial ablation using glycine irrigant," *Anaesth Intens Care* 26:112-114, 1998.
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- Nachum, A., Kol, S., Adir, Y., et al., "Massive air embolism—a possible cause of death after operative hysteroscopy using a 32% dextran-70 pump." *Fertil Steril* 58:836-838, 1992.
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